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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/014,087	01/27/98	CARLYLE W	07001/065001

EXAMINER	
PREBILIC, P	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Offic Action Summary	Application No. 09/014,087	Applicant(s) CARLYLE ET AL.	
	Examiner Paul B. Prebilic	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2000* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11, 14, 15, and 21-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 14, 15, and 21-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

Claim Obj ctions

Claims 1 and 14 are objected to because of the following informalities:

In claim 1, on line 6 and claim 14, line 6, the "and" should be changed to ---or--- since this language would more properly follow the language set forth in the MPEP for a Markush listing; see MPEP 2173.05(h). Appropriate correction is required.

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Guire (US 5,263,992) wherein the human tissue of Guire is an allograft tissue by definition and the growth factors of Guire are bound covalently with a linker molecule; the linker molecule is a crosslinker molecule, by definition because it bonds to materials at both ends; see the whole document, especially Col. 3, line 65 to Col. 4, line 50.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5-8, 25, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guire (US 5,263,992) in view of Carpentier et al (US 4,648,881).

With regard to claims 5, 6, 25, 27, and 28, Guire meets the claim language except for the use of crosslinked or uncrosslinked tissue as a base material as claimed. Carpentier et al, however, teaches that it was known to the art to use either crosslinked or uncrosslinked tissue as an implant material; see the whole document, especially Col. 3, lines 11-15. Hence, it is the Examiner's position that it would have been obvious to use crosslinked tissue to reduce host organism rejection risk or to use uncrosslinked tissue to maintain the elastic properties of the tissue when such is needed in the Guire invention.

With regard to claims 7, 8, 27, and 28, Guire meets the claim language but uses human tissue instead of porcine heart valve or bovine pericardial tissue as claimed. Carpentier et al, however, teaches that it was known to the art to use porcine heart valve or bovine pericardial tissue. Hence, it is the Examiner's position that it would have been obvious to use either tissue for the human tissue of Guire in order to reduce the cost of the implant and in order to reduce the risk of transmitting a human-specific diseases to a human patient.

Claims 9, 10, 14, 15, 21-24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guire and Carpentier et al as applied to claims 5-8, 25, 27, and 28 above, and further in view of Tisher (US 5,194,596). Guire discloses the use of various growth factors with the implant thereof but fails to disclose the use of vascular endothelial growth factor as claimed. Tisher, however, teaches that it was known to the

art to use vascular endothelial growth factor with implants. Hence, it is the Examiner's position that it would have been obvious to an ordinary artisan to use vascular endothelial growth factor as the growth factor of Guire's invention when applied to the vascular region in order to better promote cell growth in that particular area of use.

With regard to claim 24 specifically, the synthetic polymer as claimed reads on a crosslinked treated tissue which is synthetic or man-made once it is cross-linked.

Response to Arguments

Applicant's arguments filed September 1, 2000 have been fully considered but they are not persuasive.

In response to the argument that the linker molecules of Guire are not crosslinker molecules, the Examiner posits that the linker molecule is a crosslinker molecule to the extent required by the claim language because it has two reactive ends; this is a definition of a crosslinking molecule. In addition, contrary to Applicant's arguments, the claims do not require that the crosslinking agent be bound at both ends to the substrate.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "crosslinker molecules which penetrate into tissue") are not recited in the rejected claim(s); additionally, the Examiner does not see where such language has original support. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Additionally, contrary to Applicants' assertion, the Examiner posits that crosslinker molecules can activated by external entities such as heat or initiators. The Examiner will provide evidence of this fact if Applicants require such.

In response to the traversal of the Carpentier modified Guire invention, the Examiner posits that it would have been clearly obvious to an ordinary artisan to use crosslinked or uncrosslinked tissue due to its availability in the art. Furthermore, if Guire disclosed the use of crosslinked or uncrosslinked tissue, more of the claims would be anticipated instead of obvious in view thereof.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner normally can be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vincent Millin, can be reached on (703) 308-1065. The fax phone number for this Technology Center is (703) 305-3580.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.

Paul Prebilic
Primary Examiner
Art Unit 3738